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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,175	06/25/2004	Hirokazu Matsumoto	61536 (46342)	3286
21874 7590 01/12/2007 EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER CHANDRA, GYAN	
			ART UNIT	PAPER NUMBER
			1646	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		01/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/500,175

Applicant(s)

MATSUMOTO ET AL.

Examiner

Gyan Chandra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.'

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-4,7, drawn to a body weight inhibitor, weight loss agent, adipose gain inhibitor or feeding inhibitor comprising a polypeptide as represented by SEQ ID 16 and a kit for body gain inhibitor comprising a polypeptide as represented by SEQ ID NO: 16.

Groups 2-7, claim(s) 5, 6, 18-21 drawn to a method screening an agent for weight loss, weight gain inhibitor, adipose gain inhibitor or feeding inhibitor comprising using a polypeptide containing the same or substantially the same amino acid sequence as represented by SEQ ID NO: 4, 16, 126, 138, 144 or 149.

Groups 8-12, claim(s) 8, 16-17, 23 drawn to a screening kit comprising a polypeptide comprising an amino acid sequence as represented by SEQ ID NO: 4, 126, 138, 144 or 149 and a method of manufacturing a pharmaceutical composition comprising an amino acid sequence as represented by SEQ ID NO: 4, 126, 138 or 144.

Groups 13-17, claim(s) 9-11, 15 drawn to a body weight inhibitor, weight loss agent, adipose gain inhibitor or feeding inhibitor which as an agonist to a polypeptide as represented by SEQ ID NO: 4, 16, 126, 138 or 144.

Group 18, claim(s) 12, 14 drawn to a body weight inhibitor, weight loss agent, adipose gain inhibitor or feeding inhibitor comprising a polynucleotide encoding the same or substantially the same amino acid sequence as represented by SEQ ID NO: 16.

Group 19, claim(s) 13 drawn to a method of screening a body weight inhibitor, weight loss agent, adipose gain inhibitor or feeding inhibitor using a polynucleotide encoding the same or substantially the same amino acid sequence as represented by SEQ ID NO: 16.

Groups 20-24, claim(s) 22 and 24-27 drawn to a method of treating a mammal for body weight inhibition, weight loss promotion, adipose gain inhibition or feeding inhibition comprising administering to said mammal a polypeptide as represented by the SEQ ID NO: 4, 16, 126, 138 or 144.

The inventions listed as Groups 1-24 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- I. Group 1, recites the special technical feature of a body weight inhibitor, weight loss agent, adipose gain inhibitor or feeding inhibitor comprising a polypeptide as represented by SEQ ID 16 and a kit for body gain inhibitor comprising a polypeptide as represented by SEQ ID NO: 16. The polypeptide of SEQ ID NO: 16 of the instant application is identical to the polypeptide of SEQ ID NO: 16 disclosed in WO/01/98494 by Takeda Chemical Industries (see X-reference submitted with the International Search Report).
- II. Groups 2-7, recite the special technical feature of screening an agent for weight loss, weight gain inhibitor, adipose gain inhibitor or feeding inhibitor comprising

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- using a polypeptide containing the same or substantially the same amino acid sequence as represented by SEQ ID NO: 4, 16, 126, 138, 144 or 149, respectively, which is not required by other methods of Groups 19, or 20-24.
- III. Groups 8-12, recite the special technical feature of a screening kit comprising a polypeptide comprising an amino acid sequence as represented by SEQ ID NO: 4, 126, 138, 144 or 149 and a method of manufacturing a pharmaceutical composition comprising an amino acid sequence as represented by SEQ ID NO: 4, 126, 138 or 144, which is not required by other products of Groups 1, 13-17 or 18.
- IV. Groups 13-17, recite the special technical feature of a body weight inhibitor, weight loss agent, adipose gain inhibitor or feeding inhibitor which as an agonist to a polypeptide as represented by SEQ ID NO: 4, 16, 126, 138 or 144, which is not required by other products of Groups 1, 8-12 or 18.
- V. Group 18, recites the special technical feature of a body weight inhibitor, weight loss agent, adipose gain inhibitor or feeding inhibitor comprising a polynucleotide encoding the same or substantially the same amino acid sequence as represented by SEQ ID NO: 16, which is not required by other products of Groups 1, 8-12 or 13-17.
- VI. Group 19, recites the special technical feature of screening a body weight inhibitor, weight loss agent, adipose gain inhibitor or feeding inhibitor using a polynucleotide encoding the same or substantially the same amino acid sequence as represented by SEQ ID NO: 16, which is not required by other methods of Groups 2-7 or 20-24.
- VII. Groups 20-24, recite the special technical feature of treating a mammal for body weight inhibition, weight loss promotion, adipose gain inhibition or feeding inhibition comprising administering to said mammal a polypeptide as represented by the SEQ ID NO: 4, 16, 126, 138 or 144, which is not required by other methods of Groups 2-7 or 19.

The examiner has required restriction between product and process claims.

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Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1646
03 January 2007
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